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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	4

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/544,632	Hori
Examiner	**Art Unit**
Gollamudi S. Kishore, Ph.D	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The request for the correction of filing receipt dated 7-19-00 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

2. **Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific proteins listed in the specification and the cholesterol lowering effect of the complex, does not reasonably provide enablement for generic 'protein' and 'lipid metabolism improving agent' or a corresponding method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.**

It is common knowledge that there numerous proteins present in both animals and plants and instant specification is not adequately enabling to the broad term. Similarly 'lipid metabolism' includes numerous processes and instant specification is not enabling to anything other than the cholesterol lowering effect of the complex. Broad claims must have

broad basis of support in the specification; in the absence of such support, claims must be limited to specific protein-phospholipid complexes and their effect on the cholesterol.

3. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

4. **Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It is unclear what the term 'complex' is intended to convey in the context. Is it a ionic or covalent complex?

'Enzyme modified lecithin' in claim 8 is indefinite; what enzyme?

What is meant by 'functional food' in claim 13 and its dependent claims?

What is meant by 'improving' in claim 17 (also in several other claims). Compared to what? 'Metabolism' includes both catabolism and anabolism. Which one is improved?

It is unclear how the complex is recovered as recited in claims 25 and 26.

5. **Claims 19-24 provide for the use of the protein complex, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.**

Claims 19-24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 101

6. **35 U.S.C. 101 reads as follows:**

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

7. **Claims 1 and 4-8 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter.**

These claims read on natural products present both in plants and animals.

Claim Rejections - 35 U.S.C. § 102

8. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

> **A person shall be entitled to a patent unless --**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

9. **Claims 1-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dictionary of Modern Medicine (1994).**

This reference teaches naturally occurring HDL having phospholipid in claimed amounts (note page 280).

10. **Claims 1-13, and 15-24 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 61 152632.**

This reference teaches apolipoprotein A-phospholipid complex as an antiarteriosclerosis drug (Note the abstract).

11. **Claims 1-13, and 15-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988).**

These references teach complexes of hydrolyzed soybean protein and phospholipid for lowering cholesterol (note Tables in both).

Claim Rejections - 35 U.S.C. § 103

12. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

13. Claims 14 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 61 152632 or Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) cited above.

As pointed out above, these references teach the effectiveness of the complexes in lowering the cholesterol levels. The use of the complexes taught by the references either as a pharmaceutical composition or as a food additive is deemed to be the choice of the practitioner of the art and an obvious manipulatable parameter. The criticality of the hydrolysis of the protein after forming the complex is not readily apparent to the examiner. In the absence of a showing the criticality, hydrolysis of the protein before or after is deemed to be a manipulatable parameter to obtain the best possible results.

14. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (Perspectives in Biology and Medicine, 1984) in combination with either Sirtori (Ann. Nutr. Metab. 1985) or Nagaoka (Agric. Bio. Chem (1991).

Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article). Both Sirtori and Nagaoka teach the effectiveness of proteins in altering the lipid metabolism (note the abstract). It would have been obvious to combine the phospholipids of Williams with the proteins of Sirtori or Nagaoka with the expectation of obtaining at least an additive effect.

Election/Restriction

I. **Claims 1-16 are, drawn to protein-phospholipid complexes, classified in class 424, subclass 450;**

II. **Claims 17-24, drawn to uses of the complex as a lipid metabolizing agent, classified in class 514, subclass 78 and 824.**

III. **Claims 25-27 are, drawn to an enzymatic method of preparation, classified in class 436, subclass 41 plus.**

15. **The inventions are distinct, each from the other because of the following reasons: Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be prepared by hydrolysis before or after the preparation of the complex as applicants themselves are claiming..**

16. **Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different**

process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in pharmaceutical formulations or as food additive as applicants themselves are claiming..

17. **Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.**

18. **Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.**

19. **Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).**

20. **Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 10, 2001